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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,198	03/25/2004	William A. Palmisano	41543 US 0103	8645

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EXAMINER	
HARRIS, ALANA M	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,198	PALMISANO ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to a method for detecting aberrant promoter methylation comprising detecting methylation of the PAX5 α gene, classified in class 435, subclass 91.2.

II. Claims 3 and 4, drawn to a method for detecting aberrant promoter methylation comprising detecting methylation of the PAX5 β gene, classified in class 435, subclass 91.2.

III. Claim 5, drawn to a method of monitoring for cancer comprising detecting PAX5 α gene inactivation, classified in class 436, subclass 63.

IV. Claim 6, drawn to a method of monitoring for cancer comprising detecting PAX5 β gene inactivation, classified in class 436, subclass 63.

V. Claim 7, drawn to a method of monitoring for cancer comprising detecting PAX5 α gene inactivation comprising using primer sequences which recognize a bisulfite-modified DNA template, classified in class 435, subclass 91.5.

VI. Claim 8, drawn to a single-stranded DNA primer, namely SEQ ID NO: 1 for PAX5 α gene, classified in class 536, subclass 24.33. Claim 8 will be examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 1.

VII. Claim 8, drawn to a single-stranded DNA primer, namely SEQ ID NO: 2 for PAX5 α gene, classified in class 536, subclass 24.33. Claim 8 will be

examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 2.

VIII. Claim 8, drawn to a single-stranded DNA primer, namely SEQ ID NO: 5 for PAX5 α gene, classified in class 536, subclass 24.33. Claim 8 will be examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 5.

IX. Claim 8, drawn to a single-stranded DNA primer, namely SEQ ID NO: 6 for PAX5 α gene, classified in class 536, subclass 24.33. Claim 8 will be examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 6.

X. Claim 9, drawn to a single-stranded DNA primer, namely SEQ ID NO: 3 for PAX5 β gene, classified in class 536, subclass 24.33. Claim 9 will be examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 3.

XI. Claim 9, drawn to a single-stranded DNA primer, namely SEQ ID NO: 4 for PAX5 β gene, classified in class 536, subclass 24.33. Claim 9 will be examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 4.

XII. Claim 9, drawn to a single-stranded DNA primer, namely SEQ ID NO: 7 for PAX5 β gene, classified in class 536, subclass 24.33. Claim 9 will be examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 7.

XIII. Claim 9, drawn to a single-stranded DNA primer, namely SEQ ID NO: 8 for PAX5 β gene, classified in class 536, subclass 24.33. Claim 9 will be examined with this Group to the extent the primer has the specific nucleic acid sequences of SEQ ID NO: 8.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-V differ in the method objectives, method steps and parameters and/or in the reagents used.

Groups VI-XIII are structurally and functionally different products, which have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions I, III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions implement detecting a PAX5 α gene, however they differ in the method used to do such and the form of PAX5 α gene to be detected. For example, Group I detects methylation of the PAX5 α gene, whereas Group V detects inactivation of the PAX5 α gene.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the

different inventions implement detecting a PAX5 β gene, however they differ in the method used to do such and the form of PAX5 β gene to be detected. For example, Group III detects methylation of the PAX5 β gene, whereas Group IV detects inactivation of the PAX5 β gene.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions both read on detecting aberrant promoter methylation, however they assay different genes. Group I assays the PAX5 α gene and Group II assays the PAX5 β gene. Although these genes are located on the same chromosome they are transcribed from two distinct promoter and form two alternative first exons and two distinct transcription factors. Accordingly, these two Groups are not useable or searchable together.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions both read on detecting aberrant promoter methylation, however they assay different genes. Group III assays the PAX5 α gene and Group IV assays the PAX5 β gene. Although these genes are located on the same chromosome they are transcribed from two distinct promoter and form two alternative first exons and two distinct transcription factors. Accordingly, these two Groups are not useable or searchable together.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions both read on monitoring for cancer comprising detecting PAX5 αgene inactivation. Group III implements polymerase chain reaction (PCR), enzymatically replicating DNA and amplifying DNA exponentially. And Group V implements not only PCR, but bisulfite treatment of DNA. This treatment converts unmethylated cytosine bases into uracil residues and not conducted in standard PCR.

Inventions VI-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions, which read on a primer product, a nucleic acid strand, or a related molecule that serves as a starting point for DNA replication differ in nucleic acid residues and would synthesize different and distinct strands of DNA.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
06 January 2007